NOV 22 2002

510(k) Summary

Prepared: August 8, 2002 K023750

Submitter:

Company Name:	Canon USA, Inc. (U.S. agent/official correspondent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Ms. Sheila Driscoll
Phone Number:	(516) 328-5602
Fax Number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40G
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-11/CXDI-22
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K981556/K992547

Description Of Device:

The Canon digital radiography CXDI-40G is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations. The Canon digital radiography CXDI-40G is different from CXDI-11 and CXDI-22 in the following respect:

- The CXDI-40G operates in conjunction with an upright stand, table, and universal stand while the CXDI-11 operates only in conjunction with an upright stand, and the CXDI-22 only operates in conjunction with a table.

Intended Use:

Canon digital radiography CXDI-40G provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.(Table 10)

Descriptive Comparison

The predicate device is the Canon digital radiography CXDI-11 cleared under Document Number K981556 on November 4, 1998 and CXDI-22 cleared under Document Number K992547 on October 13, 1999.

The CXDI-40G's technical specifications (including image size, pixel pitch, number of pixels), imaging principle, physical characteristics and intended use are the same as those of CXDI-11 and CXDI-22. However, the differences in the design are as follows:

- The mechanical structure and physical appearance of the CXDI-40G are different than the CXDI-11 and CXDI-22. Please refer to the attached CXDI-40G comparison table provided in this section. Additional information can also be found in the CXDI-40G Operation Manual provided in this submission.
- The CXDI-40G can be used with upright stand, table, and universal stand by using the installation unit for each application, while the CXDI-11 is used with upright stand only and the CXDI-22 is only used with a table.
- A removable, fixed grid is used for the CXDI-40G, while an implemented, moving grid is used for the CXDI-11 and a removable moving grid is used for the CXDI-22. Both types of grids are used for eliminating the dispersed X-ray in exposures that use films.

(See attached Table 4.2)

Regarding the software:

- The system software for controlling CXDI-40G is released as V5.0.
- V5.0 includes some changes from V4.1.
- The main changes of the V5.0 are the addition of the control of CXDI-40G sensor and some change of GUI.
- V4.1 was first introduced and cleared under K003689 and is currently used in Canon models CXDI-11, CXDI-22, and CXDI-31.
- The comparison between V5.0 and V4.1 is described in the Software Information for model CXDI-40G section.

Based on the information in this submission, similarity to the predicate devices (Canon digital radiography CXDI-11 and CXDI-22), and the results of our design control activities, it is our opinion that the Canon digital radiography CXDI-40G described in this submission is substantially equivalent to the predicate devices

Table 10 Table of comparison

Item		CXDI-11	CXDI-22	CXDI-40G
FDA 510(k)#		K981556	K992547	Proposed Device
Intended Use		Provide diagnostic images for general radiography with upright system	Provide diagnostic images for general radiography with table system	Provide diagnostic images for general radiography
Design		Digital acquisition, electronic processing	Same	Same
Energy Uses		Receives x-radiation generated by external diagnostic x-ray generator	Same	Same
Materials	X-ray Absorber	Fluorescent screen ($Gd_2O_2S:TB^{3+}$) Visible emission peak: 545nm	Same	Same

Item		CXDI-11	CXDI-22	CXDI-40G
	Sensing Means	Amorphous Silicon W/TFT Array Detection peak: 540- 620nm	Same	Amorphous Silicon W/TFT Array Detection peak: 540- 620nm
Anatomical Sites		General radiography	Same	Same
Target Population		General population	Same	Same
Physical Safety		Minimize exposure to x-radiation	Same	Same
Compliance with Standard		Complies with IEC 601-1-2	Same	Same
Biocompatibility		N/A	N/A	N/A
Performance		After digital processing (optimize the gray-scale)	Same	Same
Labeling		Approved 510(K)	Approved 510(K)	Approved 510(K)
Pixel		2688 × 2688 pixels	Same	Same

Item	CXDI-11	CXDI-22	CXDI-40G
	(7,200,000 pixels)	Same	Same
Image size	43cm×43cm	Same	Same
Pixel pitch	160 μ m	Same	Same
MTF	MTF@2lp/mm 42%	Same	Same
Dynamic Range	Dynamic range: approximately 4 digit (linear A/D : 14bit) (output data : 12bit)	Same	Same
Grid	Moving grid	Moving grid (removable)	Stationary grid (removable)
Sensor Unit Dimension	552 x 598 x 231mm	604 x 645 x 73.5or69mm	550x 550 x 68mm

Item	CXDI-11	CXDI-22	CXDI-40G
			550x 550 x 116mm (with option parts)
Power Supply Dimension	580 x 489 x 275mm	390 x 160 x 110mm	390 x 160 x 110mm
Control PC Dimension	483.5 x 594 x 300mm	453 x 594 x 300mm	453 x 594 x 300mm
Operation Unit Dimension	298 x 209.5 x 130mm	Same	398 x 395 x 150
Card Reader Dimension	50 x 180 x 39mm	Same	Same
Stand Dimension	900 x 475 x 2100mm	N/A	(900 x 480 x 2000) *
Table Dimension	N/A	(2025 x 820 x 890) *	(2025 x 820 x 890) *

*: These dimensions are applicable for the stand and the table made by canon inc. It is possible to use another stands and tables.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc.
% Ms. Pamela K. Gwynn
Engineering Team Leader
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

AUG 23 2013

Re: K023750
Trade/Device Name: Canon Digital Radiography Model CXDI-40G
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 7, 2002
Received: November 8, 2002

Dear Ms. Gwynn:

This letter corrects our substantially equivalent letter of November 22 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

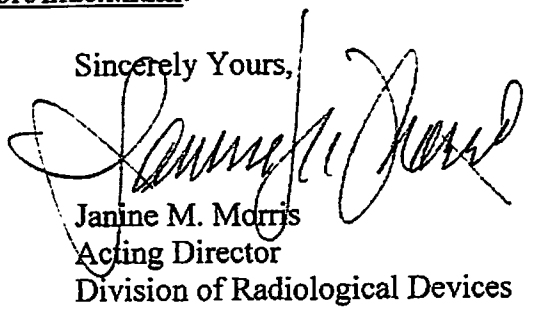
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 3: Statement

Indications Statement

510(K)Number(if known): K023750

Device Name:

Indications for Use:

CANON DIGITAL RADIOGRAPHY CXDI-40G provides digital image capture for conventional film/screen radiographic examinations.
The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use √ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023750